REMARKS

Upon entry of this Amendment and Reply, claims 21-63 are pending and claim 21 has been amended.

Applicant respectfully submits that the amendment adds no new matter. Specifically, support for claim 21 can be found on page 3, line 6 through page 6, line 31. Claim 21 is based on claim 6 of the application as filed.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 21-63 under 35 U.S.C. §112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner, in rejecting the Applicant's previously filed arguments of November 28, 2003, restated his July 29, 2003 rejections and adds:

> [W]herein Applicant's arguments assert that the core-committee is to perform all of the above functions. However, absent from the specification are guidelines/decisions by which the core-committee is to perform the above functions. For instance, by what manner/procedures (i.e. the steps of analysis/assessment/evaluation) does the core-committee review publications? What parameters define the decision process so that adjustments can be made to the rules? One of skill in the art would be unable to assess the scientific literature with out a set of guidelines by which to follow. The derivation of said "rules" is considered undue because it is unclear what the core-committee is performing procedurally with respect to the scientific literature and assessment of values. The derivation of said "rules" is not considered routine in the art and would require further inventive skill to develop said "rules". Thus, the original disclosure fails to provide one of skill in the art proper guidelines to make or use the claimed method, computer program device and computer program carrier.

See page 4, lines 3-14 of the Final Office Action dated February 24, 2004.

Applicant directs the Examiner's attention to page 3, last paragraph and page 4, first paragraph. Here the specification states:

> "More specifically, the rules of the database are based on the international (peer-received) scientific literature on HIV-resistance. The rules are updated frequently and the new rules reflect the latest publications on this subject.
> To guarantee the quality of the rules used, the updated rules are first built into a prototype of the method described. A number of independent international clinical and virological experts evaluate the new prototype running panels of clinical

samples. The feed back of all experts is then presented to a core-committee of ten experts who weigh up these contributions to determine the final rules."

See page 3, line 34 to page 4, line 18 of the application as originally filed.

As to the Examiner's rejection, Applicant is not claiming a method to derive rules from publications. Instead, Applicant claims a method for effecting computer implemented decision-support in selection of a drug therapy, whereby a rules database is used. In this regard, claim 21 has been amended to clarify that the method of the present invention "uses" a rules database, rather than "provides" a rules database.

The rules database used by the method of the present invention comprises a number of associated rules for each available drug used in treatment of a viral disease, with each rule used to give an indication the suitability of the drug for treatment of a specific viral genotype. While the quality of the rules of the database is important, the manner in which the rules are made and derived from publications is not part of the claimed method.

The Examiner raises several objections, all of which relate to the fact that the present specification does not give a detailed description of exactly how to derive each rule in the rules database. However, the applicant submits that it is not necessary for the specification to provide this level of detail because a person of ordinary skill in the art is already capable of deriving the rules to be used for the rules database and thus does not need to be taught how to do this by the present specification. See e.g. MPEP Section 2164.05(b).

For example, the rules database of the present invention may be merely a codification of the decision-making process that is already used every day by clinicians throughout the world to determine the proper drug therapy. More specifically, clinicians are required to make decisions every day about the proper drug therapy to give patients. That the clinicians are capable of making such decisions is evidenced by the fact that clinicians prescribe drug therapy for patients every day. There is no need for these clinicians to consult the present patent specification to perform this task. Instead, these clinicians employ at least their experience, common general knowledge, diagnosis, and knowledge of the medical literature to make these decisions. Also, the clinicians apply certain rules in the decision-making process to determine the weight to give to each piece of information in the final decision. Although the rules are applied in the brain of the clinician, the clinician is capable of elucidating these rules and thereby creating the database for use in the present invention.

Thus, as the specification states, the actual rule derivation process will be performed by members of a core committee who will exercise their judgment based on the information presented

to them, in much the same way that clinicians formulate drug therapies for their patients on a daily basis. Therefore, since the provision of a rules database can be carried out by skilled persons using their common general knowledge, and, in actual fact, is carried out by clinicians every day, there is no need for the specification of the present application to disclose, in detail, a specific algorithm/step/procedure for creating a specific rules database. The claims cover any method for assigning these values that involves use of the information specified in the claims, and a skilled person, exercising common general knowledge, is capable of assigning these values without requiring further guidance from the present application.

The skilled person is the clinician (primary physician) and or researcher. The skilled person is already making the required assessments in their daily practice and thus is already capable of creating the rules database without further guidance from the Applicant. Accordingly, withdrawal of the rejection under 35 U.S.C. 112, on this basis, is requested.

With regard to specific points made by the Examiner, the applicant responds as follows.

First, the present invention provides significant advantages over the current method of formulating drug therapy. The person using the method of the current invention is probably going to be a clinician (patient's physician) or a researcher. The current invention makes the formulation of a drug therapy, time effective, since the core committee, rather than the clinician or researcher, will review the relevant information, thereby saving the clinician or researcher's time for other pursuits. The current invention also makes sure that the rules database is consistently applied in the same, objective manner every time. Thus, the user knows that all relevant rules have been applied and the risk of forgetting an important rule or piece of information is eliminated.

More importantly, however, given the mass of literature currently available on, for example, HIV drug resistance, the average clinician/researcher simply cannot assimilate all the data available within a reasonable time frame and still manage his or her practice and/or research. The current invention allows the user to enter HIV or viral strain data, for example, and take advantage of the work of the core committee who has reviewed all of the relevant literature on the subject. In this manner, every clinician can formulate drug therapies in an objective manner, with access to all of the relevant information currently available on the subject. As a result, the clinician can make timely and reasonable recommendations using the method of the present invention that presumably will be better than the recommendations that are currently being made, due to having access to all relevant information and the reduced possibility for error in the application of the decision-making rules due to its implementation by a computer.

The clinician/researcher can be assured that the computer implemented decision-support not only is current and precise but also peer-reviewed and tested. The user can recommend and implement highly effective therapy with the firm knowledge that all the currently available data has been reviewed and applied to the computer implemented decision-support rules database. This frees the clinician/researcher from the risk of either missing something important in the current literature or failing to apply a rule from the rules database properly (or not at all) in determining the proper and most effective treatment course for any particular patient or experiment.

So while the clinician/researcher is perfectly capable of arriving at the same course of treatment as with the present invention, if he/she has unlimited time and resources to spend reviewing literature and developing his or her rules database, the reality is that few users actually have the time or resources to complete the generation of such a thorough rules data base. The current invention eliminates the guesswork and worry from that process and ensures fast and accurate results every time, provided that the user maintains an updated database and enters data correctly into the system.

With regards to the Examiner's specific objection that the specification does not teach how the conferred resistance by substitution is derived and a value is assigned indicative of resistance level, Applicant refers to page 3, line 31 up to page 5, line 11 of the application as originally filed. This section shows that the information on the conferred resistance by substitutions is obtained from scientific articles and evaluations by pharmaceutical companies, which information is carefully examined by the experts and core-committee. In the end the core-committee assigns a value indicating the resistance level (page 4, lines 15-18). Applicant also refers to page 4, lines 2-10 of the application as originally filed. This section indicates that the experts evaluate the new prototype by running panels of clinical samples. These experts then provide feedback to the core committee, which is composed of ten academic experts who weigh the feedback prior to determining the final rules. Since the core committee is composed of experts, these experts will be familiar with the process of formulating drug therapy, as are clinicians and persons of ordinary skill in the art, and thus will know how to create such a rules database using their common general knowledge.

As to the objection of the Examiner on how the evidence in the scientific literature is assigned to indicate confidence levels, the specification, page 5, line 35 up to page 6, line 6 clearly states the confidence levels. The scientific articles upon which the levels will be based will describe whether the drug result is based on suggestive evidence, is proven *in vitro*, or is proven *in*

vivo. Again the core-committee will finally assign the confidence level by reading the scientific articles and determining which of the confidence levels applies. Certainly, the end user is capable of making all these assessments without the aid of the current invention, and does so on a daily basis, but such an evaluation without the current invention is error-prone, time consuming and potentially subjective. Additionally, the end user is unlikely to have sufficient time or resources to accomplish the same quality of evaluation as can be provided by the core committee of experts.

As to objection of the Examiner on how to combine and weigh resistance level, drug level, confidence level, clinical experience to assign a value indicative of suitability, Applicant again refers the Examiner's attention to page 4 lines 2-10 and page 3, lines 34-36. The suitability level is the outcome of the review of all information on resistance level, drug level, confidence level and clinical experience presented to the core-committee and is based upon the knowledge of the expert members of the core-committee and their review of all of this information. Again, since the clinician, who is a person of ordinary skill in the art, already makes such assessments in their daily practice, and thus is clearly capable of carrying out this step, it is not necessary for the present specification to give a detailed discussion as to precisely how such values should be assigned.

Finally, the Examiner objects to the present claims on the basis that no specific algorithm/steps/procedures are given for derivation of the first, second and third values referred to in the claims. The reason for this is that no specific algorithm/steps/procedures are required for derivation of the first, second and third values, other than that the skilled person take into consideration certain information, as specified in the claims, in deriving those values. Since, as discussed in detail above, the skilled person already does this every day in their current practice, there is no need for the present specification to explain, in precise detail, how to go about doing this.

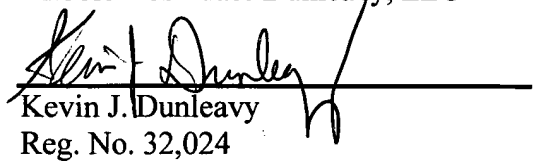
Applicant respectfully submits that upon entry of the amendment, all the claims are in condition for allowance and requests that the §112, first paragraph rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, it is believed that this application has either been placed in condition for allowance or in better form for appeal. An early action to that effect is cordially requested.

In the event that an extension of time is required, or may be required, the Commissioner is hereby requested to grant a petition for that extension of which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-0462.

Respectfully Submitted,
Knoble Yoshida& Dunleavy, LLC



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